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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,521	03/01/2005	Markus Hecker	DEBE:054US	9672

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,521	HECKER ET AL.	
	Examiner	Art Unit	
	Maria Leavitt	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-3 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claims 1 and 3 embrace a very large number of sequences for search and examination. The as-filed specification discloses that preferred DNA oligonucleotides according to the invention have a 9-mer core-binding sequence for AP-I, as contained in SEQ ID NO: 1 (p. 16, lines 31-34). However, there is nodisclosure of critical nucleotide residues of the AP-l-decoy-oligonucleotide-SEQ ID NO: 1, 2, 7 to10, or 15-34 mediating reduction of the CD40 protein content in the endothelial cells (p. 12, lines 16-30). Therefore, sequence ID Nos: 1, 2, 7 to10, or 15-34 are interpreted as distinct from each other, coding for a polypeptide having different chemical structures, physical properties, and biological functions as a result of containing different genes, which required separate searches.

Applicant is require to select one specifically named sequence from:

I. A double-strand DNA oligonucleotide of SEQ ID NO: 1, 2, 7 to10, or 15-34, as recited in claim 1.

Claim 3 is drawn to methods embracing a very large number of sequences for search and examination. The as filed specification discloses that preferred DNA oligonucleotides according to the invention have a 9-mer core-binding sequence for AP-I, as contained in SEQ ID NO: 1 (p. 16, lines 31-34). However, there is not disclosure of critical nucleotide residues of the double strand, transcription-factor-AP-1-binding DNA oligonucleotides of SEQ ID NO: 1-36. Therefore, SEQ ID NO: 1-36 are interpreted as distinct from each other, coding for a polypeptide having different chemical structures, physical properties, and biological functions as a result of containing different genes, which required separate searches.

Applicant is require to select one specifically named sequence from:

II. Transcription-factor-AP-1-binding DNA oligonucleotides of SEQ ID NO: 1-36, as recited in claim 3.

The technical feature linking Groups I to II appears to be a double-strand DNA oligonucleotide sequence that are differentially expressed in diseased grafted tissue relative to normal tissue in acute and chronic transplant rejection, acute and chronic graft-versus-host disease (GvHD) and ischemia/reperfusion damage of organs following a surgical intervention. However, sequences of isolated polynucleotides and/or genes and/or polypeptides from graft test samples of different diseases (e.g., derived from cancer, cardiovascular disease, or neurological disease) are regulated by different transcription factors in addition to AP-1 that have no substantial common core structures one from the others (e.g., TFIIA, E2F, Oct-4, Sox 2). Since

these double-strand DNA oligonucleotide sequences have different nucleotide sequences one from the others, and each nucleotide sequence becomes a basis for the "special technical feature" for that Group and not required for the other Groups, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT. Moreover, the Double-strand DNA from group I is not required for Group II, since the methods of Group II include the use of one of ID SEQ Nos. 1-36, whereas the product claims only recite a portion of these sequences.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Species Restriction.

Should group II be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above.

This application contains claims directed to the following patentably distinct species:

Prevention and/or treatment of **acute and chronic transplant rejection, acute and chronic graft-versus-host disease (GvHD)** and **ischemia/reperfusion damage of organs following a surgical intervention.**

This application contains claims directed to the following patentably distinct species: Immune related disorders.

1) Applicant is required to choose one specifically named method for the treatment of an specific disorder as recited in claim 3.

The species are independent or distinct because there drawn to diseases having different biological functions as a result of containing different expressed genes.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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ANNE M. [illegible]
PRIMARY EXAMINER